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CHEMISTRY, BIOCHEMISTRY, TOXICOLOGY, PHARMACOLOGY,
& CLINICAL CHEMISTRY

CASE EXPERIENCES: 1987-PRESENT – PLAINTIFF & DEFENSE ISSUES

TOXICOLOGY

Exposures to: Chemicals-Solvents, Toxic Gases and Poisons

ASSERTIONS

CHALLENGES

EVALUATION – CHEMICALS, GASES & POISONS – INDUSTRIAL & ENVIRONMENTAL	
Chemicals	
Medical signs and symptoms were profiled against the known toxic properties for the substance(s) found in environmental samples (toxic torts), urinary metabolites (workplace and environmental).	Chemical properties examined – vapor pressure, molecular weight, chemical reactivity with proteins and DNA. Estimates of threshold levels were made, e.g. odor threshold versus lowest adverse effect levels (LOAEL).
Qualitative and quantitative chemical analyses were requested and interpreted regarding levels of exposure. Multiple chemical interactions (e.g. immuno-suppression) were considered from these data, chemical properties and environmental assessment.	Sampling methods were evaluated and challenged when appropriate. Alternative exposures were considered (e.g. life style and hobbies) as a potential cause. Previous employment environment was advanced as the initial causation.
Solvent and toluene diisothiocyanate exposure in a closed, poorly ventilated building resulted in chronic health problems in office workers in a newly constructed building. It was shown not to be ready for occupancy.	Molds on the plenum surface of ceiling tile were shown to be unrelated to allergies and memory problems for the plaintiff. Methods used by the treating physicians were found to have no scientific validity or basis.
Toxic Gases	
The toxicity of carbon monoxide, hydrogen cyanide, hydrogen sulfide (gas and solutions), oxides of sulfur and nitrogen, hydrogen chloride was presented relating compromised pulmonary function, encephalopathy, peripheral neuropathy, and regional, selective brain damage.	Exclusion of infectious agents must be made using objective, scientifically validated clinical laboratory tests. Fluoro-deoxyglucose positron emission tomography (PET scan) data were absent in the development of abnormal brain function.
Pesticides, Insecticides, & Herbicides	
The properties of organophosphates and other reactive agents are considered as they relate to organ damage, e.g. neurotoxicity and muscular atrophy. Chronic and acute exposure models are evaluated with established symptoms. Principle toxicologist – Ellis v Maritime. Ten million dollars awarded and upheld three (3) times in the Texas Supreme Court.	Failure to establish a route of exposure was usually a strong test of scientific methodology. Estimation of dose levels was shown to be invalid. No cluster of toxic effects found and documented.
Heavy Metals	
Lead dust was shown to cause typical symptoms in children and adults exposed through an industrial exposure. A route was established through chemical analyses. Cadmium contamination of ground water has been related to toxic symptoms in a small community.	Solubility products of various metals were evaluated against known anions in the environment. Flaws in scientific methodology were discovered.

PHARMACOLOGY

ASSERTIONS

CHALLENGES

Norplant [®] was demonstrated to be similar to anabolic steroids under suspected barrier (“plug”) failure. Evaluation of the NDA data for variations in blood levels of levonorgestrel was associated with adverse physiological effects. Fruit modeling of drugs has been presented.	Good Manufacturing Procedures and quality control and assurance methods were presented in detail to demonstrate that several products did not have extreme variations in formulation and / or stability.
Antibiotic and drug allergic reaction mechanism were simplified for presentation to the jury.	<i>In vivo</i> human adverse drug effects have multiple metabolic pathways. Careful extrapolation from animal data was shown not to have occurred.
Selective serotonin re-uptake inhibitors (SSRI) have adverse effects in a small group of patients taking these drugs. Genetic variations in their metabolism may account for this phenomenon.	Patient non-compliance with a prescription drug regimen lead to transplant rejection as the primary reason for subsequent sequelæ.
Poly-pharmacy – the administration of two or more drugs that compete for metabolic sites in the liver resulted in toxicity and death.	Adequate warnings of interactions available to the treating physician such that doses could be adjusted accordingly with laboratory monitoring of the patient.
Pseudo-ephedrine warnings were found to be inadequate for a sixth-grade educated consumer. Issues regarding concerns about blood pressure and monoamine oxidase inhibitors are superficially approached.	Levo-norgestrel urinary metabolites resulted in a doping allegation. See Clinical Laboratory Practices section..
Illicit drugs use – Cocaine, marijuana, LSD, amphetamines, PCP <i>et cetera</i> caused conditions that resulted in an accident with injuries and death.	Codeine use in prescription Tylenol [®] had no relationship to the mishap at work at the docks.
Ethanol intoxication, ethanol and marijuana – with or without PCP were shown to play a role in reckless driving, injury and death.	The physiological effects of ethanol intoxication were related to the pharmacological and physiological underpinnings. The concept of “holding ones liquor” was debunked from this presentation of these scientific facts. Factors leading to pedestrian accidents with motor vehicles were developed.
Basic science issues regarding the safety of Baycol [®] were addressed relating to the inhibition lipoprotein synthesis in skeletal muscle. Electron microscopy was requested from the defendant. Serum myoglobin levels were not recommended in the direction insert to identify those patients showing signs of rhabdomyolysis.	
OxyContin and Norplant pharmacology and toxicology – controlled release device flaws. Fruit modeling.	

CLINICAL LABORATORY PRACTICES - DRUG and ALCOHOL TESTING

ASSERTIONS

CHALLENGES

Forensic and legal use of blood alcohol data from post-mortem specimens was evaluated for validity in terms of methods used – chemistry and biochemistry.	A false positive for a pregnancy test was found to be a laboratory procedural error and was not a defect in the laboratory assay kit or its manufacture..
Clinical laboratory quality control policies were found to be inadequate and not minimally meeting federal guidelines (CLIA '88).	Chain of custody issues lead results that were found inadmissible. Cross contamination factors also played a role
Screening methods for athlete drug testing were found to have no clinical relevance, since the positive specimen was simply a “spiked” negative. Positive specimens were not generated by using blood and urine specimens collected from group of healthy volunteers. Negative specimens are from a drug-group.	Antibody mold assays conducted at a physician’s office were found to be scientifically invalid. Sensitivity and specificity had not been determined. No data were analyzed to establish a cut-off level for positivity. Poor documentation resulted in a Daubert challenge.

